

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: : ATTN: PATENT
PUBLICATIONS
Dario NERI et al. : Examiner: Alana M. Harris
Serial No.: 09/194,356 : Group Art Unit: 1643
Filed: September 2, 1999 : Allowed: May 31, 2007
For: ANTIBODIES TO THE ED-B DOMAIN OF FIBRONECTIN, THEIR
CONSTRUCTION AND USES

REQUEST FOR COMPLETE NOTICE OF ALLOWANCE

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

Attached are copies of Applicants' Information Disclosure Statements and Forms PTO/SB/08A filed May 30, 2002 and February 7, 2005, copies of which have not yet been returned to applicants with the examiner's initials indicating the references cited therein were considered during the prosecution of the above-identified application, as they clearly were. It is respectfully requested that examiner-initialed copies of Forms PTO/SB/08A be returned to applicants.

Respectfully submitted,

/Anthony J. Zelano/
Anthony J. Zelano (27,969)
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Filed: June 15, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : NERI et al.

Serial No.: 09/194,356

Group Art Unit: A. M. Harris

Filed: September 2, 1999

Examiner: 1642

For: ANTIBODIES TO THE ED-B DOMAIN OF FIBRONECTIN, THEIR CONSTRUCTION AND USES

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

CITED MATERIALS

Applicant(s) hereby disclose the information listed in the attached form PTO-1449.

- ☐ Copies of materials listed but not attached were cited in parent application Serial No. _____; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an International Search Report dated _____; receipt of the International Search Report and copies of references was confirmed by the PCT International Division of the U.S. PTO in the Notice of Acceptance mailed _____.

ADDITIONAL INFORMATION

[NONE?]

LANGUAGE

- ☒ All listed materials are in the English language; see 37 C.F.R. § 1.98.
- ☐ Non-English language references:
- ☐ The reference(s): _____ in the English-language is (are) indicated by commercial data bases to correspond to the reference(s): _____, respectively.
- ☐ (An) English-language translation(s) of the references: _____ is (are) provided.
- ☐ A commercial English-language abstract of reference(s) _____ is (are) provided.
- ☐ An English-language search report or an equivalent paper from a foreign patent office translated into English in pertinent part in connection with a counterpart foreign application, is provided indicating the relevance of the cited reference(s).

FEES

- ☐ No fee is required for this Information Disclosure Statement because:
- ☐ This Information Disclosure Statement is being filed within three months of the filing date of a national application (other than a CPA) under § 1.53(d) or within 3 months of the date of entry of the national stage under § 1.491 in an international application;
 - ☐ This Information Disclosure Statement is being filed before the mailing of a first action on the merits;
 - ☐ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that closes prosecution in the application, and is accompanied by a certification below.
 - ☐ This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(i).
- ☒ A fee is required for this Information Disclosure Statement:
- ☒ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311 or an action that closes prosecution, and is accompanied by the fee set forth in § 1.17(p).
 - ☐ This Information Disclosure Statement is being filed after the mailing date of a final rejection or a notice of allowance under § 1.311 or an action that closes prosecution, but before the payment of the issue fee, and is accompanied by the fee set forth in § 1.17(p) and a certification below.

CERTIFICATION

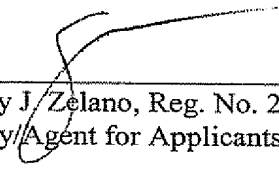
- ☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☒ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned, having made reasonable inquiry, no such item was known to any individual designated in 37 CFR § 1.56(c), more than three months prior to the filing of this statement.

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DEPOSIT ACCOUNT

If a fee is due, attached is a check in the amount of \$180.00. However, the Commissioner is hereby authorized to charge fees under 37 CFR § 1.16 and § 1.17 which may be required to facilitate this filing, or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: NOTAR-2

Date: May 30, 2002

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Complete if Known

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Sheet	1	of	2
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Application Number	9/194,356
Filing Date	September 2, 1999
First Named Inventor	NERI et al.
Group Art Unit	1642
Examiner Name	A. M. Harris
Attorney Docket Number	NOTAR-2

[illegible][illegible]

Examiner
Signature

Date
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	2	of	2
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Complete if Known

Application Number	09/194,356
Filing Date	September 2, 1999
First Named Inventor	NERI et al.
Group Art Unit	1642
Examiner Name	A. M. Harris
Attorney Docket Number	NOTAR-2

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner
Signature

Date
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dario NERI et al.

Serial No.: 09/194,356

Group Art Unit: 1642

Filed: September 2, 1999

Examiner: Alana M. HARRIS

For: ANTIBODIES TO THE ED-B DOMAIN FIBRONECTIN, THEIR CONSTRUCTION AND USES

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☐ a final rejection under 37 C.F.R. 1.113;
 - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
 - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☒ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☒ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- ☒ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated _____.

- ☒ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

- ☐ Translation of other relevant information on foreign search report

[insert necessary translation here]

Other Information

Payment of Fees Due (If Any):

- ☒ A check for \$180.00 covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

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Attorney Docket No.: ELLIS-0003

Date: February 7, 2005

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 6

Complete if Known

Application Number	09/194,356
Filing Date	September 2, 1999
First Named Inventor	Dario NERI et al.
Group Art Unit	1642
Examiner Name	Alana M. HARRIS
Attorney Docket Number	ELLIS-0003

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	1	5,734,025		KOMAI et al.	03-1998
	2	5,849,701		ROBERTS et al.	12-1998
	3	5,747,452		RUOSLAHTI et al.	05-1998
	4	5,837,813		RUOSLAHTI et al.	11-1998
	5	5,523,229		FEINBERG et al.	06-1996
	6	6,696,245		WINTER et al.	02-2004
	7	5,710,134		BOSSLET et al.	01-1998
	8	6,140,470		GAREN et al.	10-2000
	9	5,648,485		DOLPHIN et al.	07-15-1997
	10	5,817,776		GOODMAN et al.	10-06-1998
	11	5,831,088		DOLPHIN et al.	11-03-1998
	12	5,843,156		SLEPIAN et al.	12-01-1998
	13	5,877,289		THORPE et al.	03-02-1999
	14	5,913,884		TRAUNER et al.	06-22-1999
	15	5,976,535		FRITZBERG et al.	11-02-1999
	16	6,004,555		THORPE et al.	12-21-1999
	17	6,015,897		THEODORE et al.	01-18-2000
	18	6,036,955		THORPE et al.	03-14-2000
	19	6,051,230		THORPE et al.	04-18-2000
	20	6,093,399		THORPE et al.	07-25-2000

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	21	WO	9958570		Dario NERI et al.	10-18-1999		
	22	WO	0162800		Dario NERI et al.	08-30-2001		
	23	JP	0276598		SEKIGUCHI et al.	03-15-1990		√
	24	JP	4169195		SEKIGUCHI et al.	06-17-1992		√
	25	WO	9745544		Medical Res Council	12-04-1997		
	26	WO	96/23816		CREIGHTON et al.	08-08-1996		
	27	EP	184187		KUDO et al.	06-11-1986		
	28	EP	239400		WINTER et al.	09-30-1987		
	29	EP	0120694		BOSS et al.	10-03-1984		
	30	WO	94/13804		HOLLIGER et al.	06-23-1994		
	31	WO	93/11161		WHITLOW et al.	06-10-1993		

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Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

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STATEMENT BY APPLICANT**

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Sheet

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of

6

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First Named Inventor	Dario NERI et al.
Group Art Unit	1642
Examiner Name	Alana M. HARRIS
Attorney Docket Number	ELLIS-0003

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	40	TOMOHIKO FUKUDA ET AL., "Mice lacking the EDB segment of fibronectin develop normally but exhibit reduced cell growth and fibronectin matrix assembly in vitro," Cancer Research, 1 October 2002, pages 5603-5610, vol. 62.	
	41	ANDREW GRIFFITHS ET AL., "Isolation of high affinity human antibodies directly from large synthetic repertoires," The EMBO Journal, 1994, pages 3245-3260, vol. 13, no. 14.	
	42	Dario NERI et al., "Targeting by affinity-matured recombinant antibody fragments of an angiogenesis associated fibronectin isoform", Nature Biotechnology, Vol. 15, November 1997, pages 1271-1275	
	43	Dario NERI et al., "Affinity reagents against tumour-associated extracellular molecules and newforming vessels," Advanced Drug Delivery Reviews, 6 April 1998, pages 43-52, vol. 31, no. 1-2, XP002124780, pages 46, right-hand column, page 49, left-hand column.	
	44	PINI, A., et al., "Design and use of a phage display library. Human antibodies with subnanomolar affinity against a marker of angiogenesis eluted from a two-dimensional gel," Journal of Biological Chemistry, August 21, 1998, pages 21769-21776, Vol. 273, no. 34, XP002124781.	
	45	VITI F. ET AL., "Increased Binding Affinity and Valence of Recombinant Antibody Fragments Lead to Improved Targeting of Tumoral Angiogenesis," Cancer Research, 15 January 1999, pp. 347-352, vol. 59, no. 2, XP002124782, the whole document.	
	46	R. FATTORUSSO ET AL., "NMR structure of the human oncofetal fibronectin ED-B domain, a specific marker for angiogenesis", 15 April 1999, Structure, pp. 381-390, vol. 7, no. 4, XP002124783.	
	47	TARLI L ET AL., "A high-affinity human antibody that targets tumoral blood vessels," Blood, 1 Jul 1999, pages 192-8, vol. 94, no. 1, XP002124784.	
	48	M. ZALUTSKY ET AL., "Labeling monoclonal antibodies and F(ab')2 fragments with the alpha-particle-emitting nuclide astatine-211: preservation of immunoreactivity and in vivo localization," Proceedings of the National Academy of Sciences in the U.S.A., September 1989, vol. 86, no. 18, pages 7149-7153, XP002172060, Washington DC, USA, abstract.	
	49	S. LINDEGREN ET AL., "Chloramine-T in high-specific-activity radioiodination of antibodies using N-succinimidyl-3-(trimehtylstannyl)benzoate as an intermediate," Nuclear Medicine and Biology, October 1998, pages 659-665, vol. 25, no. 7, XP004149436, Oxford, GB, abstract.	
	50	M. BIRCHLER ET AL., "Selective targeting and photocoagulation of ocular angiogenesis mediated by a phage-derived human antibody fragment," Nature Biotechnology, October 1999, pages 984-988, vol. 17, no. 10, XP002172061, New York, NY, USA, the whole document.	
	51	Judah FOLKMAN, "Angiogenesis in cancer, vascular, rheumatoid and other disease", Nature Medicine, Vol. 1, Number 1, 1995, pages 27-31	
	52	Renata PASQUALINI et al., "α-Vintegrins as receptors for tumor targeting by circulating ligands", Nature Biotechnology, Vol. 15, June 1997, pages 542-546.	
	53	Michael S. O'REILLY et al., "Angiostatin induces and sustains dormancy of human primary tumors in mice", Nature Medicine, Vol. 12, Number 6, June 1996, pages 689-692	

54	Xianming HUANG et al., "Tumor Infarction in Mice by Antibody-Directed Targeting of Tissue Factor to Tumor Vasculature", <i>Science</i> , Vol. 275, January 24, 1997, pages 547-550	
55	Dario NERI et al., "Biophysical methods for the determination of antibody-antigen affinities", <i>Tibtech</i> (Vol. 14), December 1996, pages 465-470	
56	E. Sally WARD et al., "Binding activities of a repertoire of single immunoglobulin variable domains secreted from <i>Escherichia coli</i> ", <i>Nature</i> , Vol. 341, No. 6242, October 12, 1989, pages 544-546.	
57	James S. HUSTON, et al., "Protein engineering of antibody binding sites: Recovery of specific activity in an anti-digoxin single-chain Fv analogue produced in <i>Escherichia coli</i> ", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 85, August 1988, pages 5879-5883	
58	Philipp HOLLIGER, et al., "Diabodies: Small bivalent and bispecific antibody fragments", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 90, July 1993, pages 6444-6448	
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60	Cyrus CHOTHIA, et al., "Canonical Structures for the Hypervariable Regions of Immunoglobulins", <i>Journal of Molecular Biology</i> , Vol. 196, No. 4, August 20, 1987, pages 901-917	
61	D. NERI, et al., "Multipurpose High Sensitivity Luminescence Analyzer (LUANA): Use in Gel Electrophoresis", <i>Biotechniques</i> , Vol. 20, No. 4, April 1996, pages 708-712	
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63	Johnathan P. L. COX, et al., "A directory of human germ-line V _x segments reveals a strong bias in their usage", <i>European Journal of Immunology</i> 4/1994, pages 827-836	
64	James D. MARKS, et al., "By-passing Immunization Human Antibodies from V-gene Libraries Displayed on Phage", <i>Journal of Molecular Biology</i> , Vol. 222, No. 3, December 5, 1991, pages 581-597	
65	Hennie R. HOOGENBOOM, et al., "Multi-subunit proteins on the surface of filamentous phage: methodologies for displaying antibody (FAB) heavy and light chains", <i>Nucleic Acids Research</i> , Vol. 19, No. 15, August 11, 1991, pages 4133-4137	
66	Dario NERI, et al., "Radioactive labeling of recombinant antibody fragments by phosphorylation using human casein kinase II and [γ - ³² P]-ATP", <i>Nature Biotechnology</i> , Vol. 14, No. 4, April 1996, pages 485-490	
67	Robert SCHIER, et al., "Identification of functional and structural amino-acid residues by parsimonious mutagenesis" <i>Gene</i> , Vol. 169, (1996), No. 2, pages 147-155	
68	Wataru ITO, et al., "Mutations in the Complementarity-determining Regions do not cause Differences in Free Energy during the Process of Formation of the Activated Complex between an Antibody and the Corresponding Protein Antigen", <i>Journal of Molecular Biology</i> , Vol. 248, No. 4, May 12, 1995, pages 729-732	
69	C. HAMERS-CASTERMAN, et al., "Naturally occurring antibodies devoid of light chains", <i>International Weekly Journal of Science</i> , Vol. 363, NO. 6428, June 3, 1993, pages 446-448	
70	U. JÖNSSON, et al., "Real-Time Biospecific Interaction Analysis Using Surface Plasmon Resonance and a Sensor Chip Technology", <i>Biotechniques</i> , Vol. 11, No. 5, November 1991, pages 620-627	
71	Ahuva NISSIM, et al., "Antibody fragments from a 'single pot' phage display library as immunochemical reagents", <i>The Embo Journal</i> , Vol. 13, No. 3, February 1, 1994, pages 692-698	
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